

In re Application of: **STAMFORD** et al.
Serial No.: 10/026,651
Filed: December 18, 2001

Remarks

This paper is in response to the Official Action dated May 16, 2003, for the above-identified application. A response to the office action was originally due on August 16, 2003. Applicants are filing this response with a request for a one-month extension of time, herein attached, thus making this response due on September 16, 2003.

Claims 1-31 are pending in the application. Claims 5-11 and 15-20 have been withdrawn from consideration. Claims 1-4 and 21-31 have been rejected. Claims 12-14 and 30 have been objected to. No claims have been allowed. Applicants have amended claims 1-3, 12-14, 22, 25 and 27-29. Applicants have canceled claims 5-11, 15-21 and 30. No new subject matter has been added to the subject application with the filing of this response. Applicants reserve their right to file divisional applications on the subject matter that has been subject to restriction and continuation applications on the subject matter that has been deleted out of all currently amended claims.

Restriction Requirement

The Examiner stated that claims 5-11 and 15-20 are being withdrawn from further consideration as being directed to non-elected matter. The Examiner rejected applicants' response to the restriction and stated that the restriction requirement as indicated is proper and thereby made final.

In response, applicants have cancelled claims 5-11 and 15-20 without prejudice to applicants' rights. Further, applicants have amended claims 1-3 as required by the Examiner's restriction requirement.

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35 USC §112, 2nd Paragraph

The Examiner stated that claims 1-4 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, because the recitation of "prodrug" in said claims is deemed indefinite for more than one reason. The Examiner stated that while the recitation of prodrugs is acceptable and would include esters, amides alkoxycarbonyl, etc., the Examiners stated that rejected claims 1-4 and 12-14 already include the definition included in prodrugs.

In response, applicants have amended claims 1, 12-14, 22, 25 and 27-29 to remove the term prodrugs and any reference to the term prodrugs, thus mooted the Examiner's rejection. Applicants respectfully request the withdrawal of this rejection.

35 USC §112, First Paragraph

The Examiner stated that claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the Examiner believes that the specification, while being enabling for eating disorders, does not provide enablement for any or all metabolic disorders including those yet to be discovered as due to NP Y Y5 receptor activity.

The Examiner stated that, the following different factors (see Ex parte Forman, 230 USPQ at 547; Wands, In re. 858.F. 2d 731. 8 USPQ 2d 1400. Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed factors such as quantity of experimentation necessary, predictability in the art, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

For the reasons set forth below, the rejection respectfully is traversed.

Applicants respectfully note that the general knowledge in the art recognizes the utility of NP Y Y5 antagonists for obesity and related disorders (see for example cited art on first page of applicants specification). Applicants respectfully suggest that other metabolic disorders that are regulated by the NP Y Y5 receptor, are enabled by the art and the specification. In support of this, applicants refer the Examiner to the following references cited on page 1 of the specification. Copies of

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these references have been provided to the Examiner in an IDS filed on May 21, 2003.

Central administration of NPY to animals dramatically increased food intake and decreased energy expenditure (Stanley, B. and Leibowitz, S., Proc. Natl. Acad. Sci. USA 82: 3940, 1985; Billington et al., Am J. Physiol., 260, R321, 1991). These effects are believed to be mediated at least in part by activation of the NPY Y5 receptor subtype. Additionally, it has been reported that activation of the NPY Y5 receptor by administration of the Y5 – selective agonist [D-Trp³²]NPY to rats stimulates feeding and decreases energy expenditure (Gerald, C. et al., Nature, 1996, 382, 168; Hwa, J. et al., Am. J. Physiol., 277 (46), R1428, 1999). Hence, compounds that block binding of NPY to the NPY Y5 receptor subtype should have utility in the treatment of eating disorders such as obesity, bulimia nervosa, anorexia nervosa, and in the treatment of disorders associated with obesity such as type II diabetes, insulin resistance, hyperlipidemia, and hypertension.

Published PCT patent application WO 00/27845 describes a class of compounds, characterized therein as spiro-indolines, said to be selective neuropeptide Y Y5 receptor antagonists and useful for the treatment of obesity and the complications associated therewith. Known urea derivatives indicated as possessing therapeutic activity are described in U.S. Patent Nos. 4,623,662 (antiatherosclerotic agents) and 4,405,644 (treatment of lipometabolism).

With regard to the other disorders, applicants particularly point out that is well known in the art that in addition to the direct effects of administering NP Y Y5 compounds for weight loss, there are diseases and conditions that will benefit from the weight loss such as type II diabetes, insulin resistance, hyperlipidemia, and hypertension. (see specification, page 1, lines 24-27) Thus contrary to the Examiner's rejection, applicants suggest that the novel NP Y Y5 compounds claimed herein are enabled and therefore, applicants respectfully request the withdrawal of this rejection.

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Claim Objections

The Examiner has objected to claim 30 under 37 CFR 1.75 as being a substantial duplicate of claim 21. In response, applicants have canceled claim 30. Applicants respectfully request the withdrawal of this objection.

Allowable Subject Matter


The Examiner stated that claims 12-14 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, applicants respectfully point out that they have amended the base claim 1 and claims 12-14 themselves in an effort to place these claims in condition for allowance. Therefore, applicants respectfully request the withdrawal of this objection.

Applicants respectfully submit that in view of the above response, applicants have sufficiently addressed the Examiner's rejections, objections and that the application, as amended, is in condition for allowance.

If any additional fees are determined to be due by this paper, the Commissioner is hereby authorized to deduct such fees from **Account No. 19-0365**.

The Examiner is requested to call the undersigned attorney on any matter connected with this application.

Respectfully submitted,



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